§158.1010. The table notes are shown in paragraph (e) of this section.

TABLE—APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline Number	Data requirement	Use pattern		Test substance	Test Note No.
		Occupational	Residential		
875.1100	Dermal outdoor exposure	R	R	TEP	1, 2, 3
875.1200	Dermal indoor exposure	R	R	TEP	1, 2, 4
875.1300	Inhalation outdoor exposure	R	R	TEP	1, 2, 3
875.1400	Inhalation indoor exposure	R	R	TEP	1, 2, 4
875.1500	Biological monitoring	CR	CR	TEP	1, 2
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	--

(e) *Test notes.* The following notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data, provided the human pharmacokinetics of the pesticide and/or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.

3. Data are required if the product is applied outdoors.

4. Data are required if the product is applied indoors.

5. Data reporting and calculations are required when handler exposure data are submitted.

§ 158.1050 Post-application exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration, provide adequate protection for a particular pesticide use pattern, post-application exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing before the initiation of studies.

(b) The Agency may accept surrogate exposure data from other sources to satisfy post-application exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific needs of EPA. In order to be acceptable, among other things, the Agency must find that the surrogate exposure data have adequate information to address post-application exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the post-application activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

§ 158.1060 Post-application exposure—criteria for testing.

Exposure data described in §158.1070(d) are required based upon toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, either or both of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse health effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from post-application exposure to the pesticide.

(b) *Exposure criteria.* The need for data from potential exposure resulting